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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/060,849	01/30/2002	Stephen Mark McAllister	P51223	9605

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EXAMINER

OH, SIMON J

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 10/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/060,849

Applicant(s)

MCALLISTER ET AL.

Examiner

Simon J. Oh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35,38-40 and 71-113 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35,38-40 and 71-113 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's amendment and response, both received on 19 July 2006.

Claim Objections

The objections to Claims 31-35, 71 and 72 are hereby withdrawn.

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claim 31 under 35 U.S.C. 112, second paragraph, is hereby withdrawn.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1-35, 38-40 and 71-111 under 35 U.S.C. 103(a) as being unpatentable over Hatano *et al.* in view of Lehmann I and Lehmann II is maintained.

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Claims 112 and 113 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hatano *et al.* (U.S. Patent No. 6,309,666 B1) in view of Lehmann I (U.S. Patent No. 5,705,189) and Lehmann II (U.S. Patent No. 5,644,011)

The Hatano *et al.* patent teaches coated capsule compositions comprising a hard outer shell (See Abstract). Suitable materials for the outer shell include methacrylate co-polymers and acrylic co-polymers (See Column 5, Line 42 to Column 6, Line 23). Each of the components of the capsule, including the hard outer shell, may include various excipients, including binders, disintegrants, lubricants, aggregation-preventing agents, plasticizer, and a surfactant. Excipients include lactose and starch. Binders include ethylcellulose, HPMC, and polyethylene glycol. Disintegrants include polyvinylpyrrolidone. Lubricants and aggregation-preventing agents include talc, magnesium stearate, and colloidal silicon dioxide. Plasticizers include diethyl phthalate, dibutyl phthalate, and polyethylene glycol. Surfactants include polyoxyethylene sorbitan monooleate, polyoxyethylene hydrogenated castor oil, and sodium dodecyl sulfate (See Column 11, Line 52 to Column 12, Line 65). Such additives may be added in any amount within the scope of the knowledge of one of ordinary skill in the art (See Column 13, Lines 3-5).

The Hatano *et al.* patent does not disclose a molding process for making the disclosed hard outer capsule shells, nor does it disclose the use of a copolymer of methyl acrylate, methyl methacrylate, and methacrylic acid in a ratio of 7:3:1.

The Lehmann I patent discloses processes for producing acrylic and/or methacrylic articles, such as capsules, by molding (See Column 2, Line 53 to Column 3, Line 32). The articles may have various excipients blended into the melt, such as plasticizers, fillers, and mold-release agents, such as glycerol monostearate (See Column 3, Line 62 to Column 4, Line 2). The

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process can produce articles with thicknesses ranging from 0.1 to 1 mm (See Column 3, Lines 10-13)

The Lehmann II patent discloses a copolymer containing 40% to 70% of methyl acrylate, 20% to 40% of methyl methacrylate, and 10% to 25% of methacrylic acid (See Abstract). The release characteristics of this copolymer make it suitable for release of an active agent at specific points in the gastrointestinal tract, as well as other body cavities, tissues, and the bloodstream (See Column 1, Line 64 to Column 2, Line 2; and Column 4, Lines 51-59)

It is the position of the examiner that there is sufficient motivation within the prior art for combining the prior art references. The Lehmann I patent teaches that the molded articles disclosed therein can be combined with other molded articles for the manufacture of a dosage form having a particular desired release profile (See Lehmann I, Column 3, Lines 21-36). Thus, one of ordinary skill in the art would be motivated to combine the references to incorporate the molding techniques of the Lehmann I patent into the disclosure of the Hatano *et al.* patent in order to give one of ordinary skill in the art a greater degree of control in fashioning capsules that exhibit a particularly desired release characteristic.

As the Lehmann I and the Hatano *et al.* prior art references disclose compositions incorporating various excipients for the purpose of imparting certain characteristics as desired by one of ordinary skill in the art, the references are considered to be analogous art. Thus, there is a reasonable expectation of success in combining the prior art references of record

One of ordinary skill in the art would also be motivated to combine the Lehmann II patent and the Hatano *et al.* patent in order to incorporate the release characteristics imparted by the copolymer of the Lehmann II patent into the pharmaceutical dosage form disclosed in Hatano

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et al., as the Hatano *et al.* patent makes use of acrylic copolymers in order to formulate a dosage form with a particular desired release characteristic. Thus, there is a reasonable expectation of success in combining the Lehmann II and Hatano *et al.* references. Therefore, the instantly claimed invention is *prima facie* obvious.

Response to Arguments

Applicant's arguments filed 19 July 2006 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

With regard to the applicant's arguments on page 30 against the Hatano *et al.* reference, the examiner disagrees with the assessment that the disclosure of this reference is "clearly in direct contrast" to the subject matter of the instant claims. Primarily, the Hatano *et al.* reference shows that it is known in the art to use methacrylate copolymers with the same excipients as those recited in the instant claims for use in capsule compositions.

Regarding the applicant's arguments on page 31 against the Lehmann II reference, it is argued that the reference alone does not describe actual steps for injection molding. By the applicant's own admission, the disclosure of the Lehmann II reference shows that the capsule compositions disclosed therein are suitable for melt- processing. Thus, the examiner also relies on the Lehmann I reference to show that it is known in the art for methacrylate copolymers to be

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processed by molding techniques for use as capsule compositions. This reference also discloses thicknesses for such compositions ranging from 0.1 mm to 1.0 mm, as detailed in the above rejection.

Regarding the applicant's arguments on page 32 concerning the lack of an explicit disclosure of pH-independent functionality, the examiner would like to point out that the collective disclosure of the prior art has shown the instantly claimed composition. The Hatano *et al.* reference shows capsule compositions containing methacrylate copolymers for use as capsule compositions, with the same excipients as those recited by the applicant. The Lehmann II reference has shown a methacrylate copolymer that reads on the one recited in the instant claims. Finally, the Lehmann I reference has shown that methacrylate copolymers may be processed with molding techniques for use as capsule compositions. Thus, the collective disclosure of the prior art has shown the instantly claimed composition. As such, functional limitations such as pH-independent release are met, since a composition cannot stand apart from its properties.

Regarding the applicant's arguments on page 33 on the deficiencies of the Lehmann I reference with regard to DME agents, surfactants, and super disintegrants, such excipients are within disclosure of the Hatano *et al.* patent, as detailed in the above prior art rejection.

The applicant then attacks the examiner's motivation for combining the references. First, the applicant alleges that no motivation is present in either Lehmann I or Lehmann II for including the excipients disclosed in the Hatano *et al.* reference. The applicant then alleges that there is no guidance or motivation for modifying the Hatano *et al.* reference for using a thermoplastic polymer for molding capsule shells. However, the applicant then admits on the record at the top of page 34 that Lehmann I discloses the need for a plasticizer and mold-

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releasing agent. However, these are disclosed along with dissolution modifying excipients, surfactants, and super disintegrants within the Hatano *et al.* patent. It is the position of the examiner that one of ordinary skill in the art would be motivated to combine the references to incorporate the molding techniques of the Lehmann I patent into the disclosure of the Hatano *et al.* patent in order to give one of ordinary skill in the art a greater degree of control in fashioning capsules that exhibit a particularly desired release characteristic. The incorporation of the additives disclosed in Hatano *et al.* are recognized by the art as being useful for use in capsule compositions, and one of ordinary skill in the art can readily determine which particular excipients are suitable for a particular use.

Much of the applicant's arguments against the individual references and the prior art rejection as a whole are centered on the alleged failure of the prior art to disclose the particular steps with which the instantly claimed compositions are formulated by molding. Thus, the applicant appears to be arguing from a product-by-process perspective. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted)

In the view of the examiner, it is the collective disclosure of the prior art that shows the various components of the instantly claimed compositions. Furthermore, despite the applicant's process-by-product arguments, such limitations are clearly absent from the instant claims.

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Therefore, the applicant's arguments are not commensurate with the scope of the instant claims. As the prior art has taught or suggested each and every component as set forth by the scope of the instant claims, the instantly claimed invention is deemed *prima facie* obvious. All pending claims are rejected.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (571) 272-0599. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

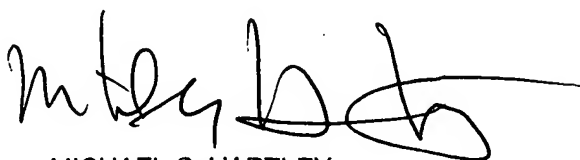
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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Simon J. Oh
Examiner
Art Unit 1618

sj0



MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER